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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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JANELLE D WAACK
ARNOLD WHITE AND DURKEE
P O BOX 4433
HOUSTON TX 77210-4433

18N2/1015

EXAMINER	
PAK, M	
ART UNIT	PAPER NUMBER
1812	8

DATE MAILED: 10/15/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 6-25-97, PAPER NO. 7

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-6, 8-13, 15-20 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-6, 8-13, 15-20 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

1. The amendments filed 25 June 1997, filed Paper No. 7, has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicant's arguments filed 25 June 1997, filed Paper No. 7, have been fully considered but they are not found persuasive.

Double Patenting

Claims 1-2, 8-9, and 15-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-9, 14-17, and 22-24 of copending Application No. 08/398,852. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth in the last office action and set forth below.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant argues that because 08/398,852 encompasses treatment of diabetic peripheral neuropathy which is a distinct invention from claims 1-2, 8-9, and 15-16 of the present application which encompasses the treatment of the CNS. However,

the claims 1-2, 8-9, and 15-16 of the present application differ only by the preamble recitation of the therapeutic objective. The method defined by the process steps which are not different.

Claim Rejections - 35 USC § 112

4. Claims 1-4, 8-11, and 15-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of parenteral administration of IGF-I, IGF-II, or a combination of both IGF-I and II for the treatment of locus ceruleus noradrenergic neurons ablation by 6-hydroxydopamine, does not reasonably provide the full scope of enablement for parenteral administration of IGF-I or IGF-II, for effecting any changes in the biochemistry or function of the central nervous system (CNS) or spinal cord and treating any disorders or diseases in the brain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the reasons set forth in the last office action and set forth below.

The amended claim limitation of effecting a change in the "biochemistry and function" of CNS encompass effecting all changes in the CNS which includes molecular, physiological, cellular, and behavioral changes by administering IGF-I or IGF-II under normal or disordered conditions.

Applicant argues that the examples in the specification is reasonably predictive of the inventive methods applicability to a wide range of brain disorders and diseases. However, as discussed in the last office action, the references of Baringa (A34), Jackowski(R), and Shepherd(S) provide the state of the art before and after the time of the invention that treatments of nervous system diseases with neurotrophic factors are unpredictable and that treatment of any one disease is not predictive of another.

Applicant argue that several scientific references clearly demonstrate the applicability of IGF treatment to a wide variety of brain and spinal cord tissues. It should be noted that Mooney et al. and Thorton et al. references were not attached and missing from the file. The examiner could not order the references because no citation of the references were provided. Furthermore, applicant admits that all the references including Gluckman et al.(A62) does not provide an enabling description of parenteral administration(page 4 of the response filed 25 June 1997, Paper No. 7). Examiner agrees that Lewis et al.(A1) does not teach the full scope of a method to effect a change for all biochemistry and function of the CNS, but only those taught in the reference, some of which are outlined in 35 U.S.C. 102(e) rejection below. However, Lewis et al.(A1) does teach parenteral adminstration(column 4, lines 41-50).

5. Claims 1-4, 8-11, and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 8-11 recite "effecting a change in the biochemistry or function" of the CNS which is confusing and ambiguous because the biochemistry and function of the CNS would not be reasonably expected to change in the CNS.

Claims 19 and 20 recite "an amount effective to treat" which is ambiguous and confusing because it is not clear what is being treated.

Claim Rejections - 35 USC § 102

6. Claims 1-6, 8-13, and 15-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Lewis et al.(A1) for the reasons set forth in the last office action and set forth below.

Applicant argues that Lewis et al. does not provide an enabling disclosure because Lewis et al. lack any showing of an IGF acting across the blood-brain barrier. However, Lewis et al. teach all the limitations of the claims, and without specific evidence to the contrary Lewis et al. teachings are enabling. Lewsi et al. teaches the species of the larger genus of claims 1, 8, and 15.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Cephalon, Inc.(B2) is a cumulative reference with Lewis et al.(A1).

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Since the fee set forth in 37 CFR 1.17(r) for a first submission subsequent to a final rejection has been previously paid, applicant, under 37 CFR 1.129(a), is entitled to have a second submission entered and considered on the merits if, prior to abandonment, the second submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a second submission and the appropriate fee for a small entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. If a notice of appeal and the appeal fee set forth in 37 CFR 1.17(e) were filed prior to or with the payment of the fee

set forth in 37 CFR 1.17(r), the payment of the fee set forth in 37 CFR 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 CFR 1.129(a). In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Pak whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**stephen.walsh@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MDP

Michael D. Pak
1812
9 October 1997

DAVID L. FITZGERALD
PRIMARY EXAMINER
GROUP 1800